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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/824,011

04/14/2004

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08/18/2008

EXAMINER

PATEL, NATASHA

ART UNIT

PAPER NUMBER

3766

MAIL DATE

DELIVERY MODE

08/18/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/824,011	Applicant(s) SOYKAN ET AL.	
	Examiner NATASHA N. PATEL	Art Unit 3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 March 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 20-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 20-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 April 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The amendment filed on 3/6/08 has been received and considered. By this amendment, Claims 1-19 are cancelled and Claim 20 is amended. Claims 20-25 are now pending in the application.

Priority

Examiner withdraws priority rejections made in the last Office Action in view of the corrected and updated declaration. No foreign priority is given to the application at hand.

Specification

In view of the Applicant's amendment to the Specification, Examiner withdraws the objections that were made in the previous Office Action.

Oath/Declaration

In view of the Applicant's filing of a new oath and declaration, Examiner withdraws the objection that was made in the previous Office Action.

Double Patenting

In view of the Applicant's submission of a terminal disclaimer, the Examiner withdraws the rejections made in the previous Office Action.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the

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applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claim 20 is rejected under 35 U.S.C. 102(e) as being anticipated by Taheri et al. (US Patent 6,690,970).

3. Regarding Claim 20, Taheri discloses repair of the heart myocardium of a patient, the method comprising:

(a) providing an implantable system comprising:

(i) a cell repopulation source comprising genetic material, stem cells, or a combination thereof, capable of forming new contractile tissue in and/or near an infarct zone of a patient's myocardium (see col. 3, lines 2-7); and

(ii) an electrical stimulation device for electrically stimulating the new contractile tissue in and/or near the infarct zone of the patient's myocardium (see col. 5, lines 46-52);

(b) implanting the cell repopulation source into and/or near the infarct zone of the myocardium of a patient (see col. 5, line 66-col. 6, line 7);

(c) allowing sufficient time for new contractile tissue to form from the cell repopulation source (see col. 5, lines 25-30); and

(d) electrically stimulating the new contractile tissue (see col. 5, lines 46-52).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 21-22 and 24-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Taheri et al. (US Patent 6,690,970) in view of Michal et al. (US Patent 7,294,334).

6. Regarding Claims 21 and 22, Taheri discloses an electrical stimulation device (see pacemaker; col. 5, lines 46-52). Taheri does not go into the specifics of the stimulation device. Michal discloses a similar system where the stimulation device comprises a muscle stimulator and electrodes; wherein the electrodes are implanted into and/or near the infarct zone of the myocardium (see col. 10, lines 19-44). It would have been obvious to one of ordinary skill in the art at the time of the invention to set up the electrical stimulation device in such a manner because Michal teaches that doing so unloads the infarct region from mechanical stress (see col. 10, lines 32-39). The examiner considers that any pacemaker would be in the form of a capsule since a capsule is merely a small case or covering (see *Random House Unabridged Dictionary*, © *Random House, Inc. 2006*).

7. Regarding Claim 24, modified Taheri discloses the muscle stimulator and cell repopulation source are delivered to the infarct zone through a catheter (see col. 5, lines 55-59).

8. Regarding Claim 25, Taheri discloses the undifferentiated contractile cells comprise autologous cells (see col. 3, lines 4-5).

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9. Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Taheri et al. (US Patent 6,690,970) and Michal et al. (US Patent 7,294,334) in view of Padua et al. (US PGPub. 2003/0204206).

10. Regarding Claim 23, neither Taheri nor Michal discloses combining the stimulator with the delivery of the cell repopulation source. Padua teaches a similar system where the muscle stimulator is a carrier for the cell repopulation source (see par. 10). It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the two in order to avoid stimulating the wrong location and to prevent multiple insertions.

Conclusion

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

12. Lee (PG Pub. 2004/0002740): conduction blocks created for increased contractility and conductivity on cardiac tissue.

13. Girouard et al. (PG Pub. 2005/0288721): pacing and biological therapy for MI patients.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NATASHA N. PATEL whose telephone number is (571)272-5818. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carl H. Layno can be reached on 571-272-4949. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Natasha N Patel/
Examiner, Art Unit 3766

/Carl H. Layno/
Supervisory Patent Examiner, Art
Unit 3766